UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
HARRISONBURG DIVISION

UNITED STATES OF AMERICA	)	Civil Action No. 5:16cv76
	)	
	)	
v.	)	
	)	CONSENT DECREE
	)	OF CONDEMNATION AND
All 50 pound high heat nonfat dry milk powder (Grade A) labeled in part "NON-FAT DRY MILK GRADE A-HIGH HEAT MANUFACTURED BY: Valley Milk Products, STRASBURG, VIRGINIA 22657 PERMIT NO. 51-4136 NET WEIGHT- 50 LBS. BAG NO. LOT NO." ….	)	PERMANENT INJUNCTION
	)	
Defendants *in rem*	)	
	)	
and	)	
	)	
Valley Milk Products, LLC, and Michael W. Curtis, Robert D. Schroeder, and Jennifer J. Funkhouser, individuals	)	
	)	
Defendants.	)	

On November 18, 2016, a Complaint for Forfeiture against the above-described articles was filed in this Court on behalf of the United States of America by John P. Fishwick, Jr., United States Attorney for the Western District of Virginia, and Joseph W.H. Mott, Assistant United States Attorney. The Complaint alleges that the articles proceeded against are articles of food, within the meaning of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(f), which are adulterated while held for sale after shipment of one or more of their components in interstate commerce, 21 U.S.C. § 342(a)(4). The Complaint further alleges that the defendant articles of food are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have

been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth and/or may have been rendered injurious to health.

Pursuant to the Warrant for Arrest issued by this Court, the United States Marshal for this District seized the articles on November 22-23, 2016. Thereafter, Valley Milk Products, LLC ("Claimant"), intervened and filed a claim to the seized articles.

Claimant affirms that it is the sole owner of the seized articles of food and that no other person has an interest in the goods. Further, Claimant shall indemnify and hold the plaintiff harmless should any party or parties hereafter file or seek to file a claim to intervene in this action, and obtain any part of the articles subject to this Decree or assert any claim against plaintiff arising from the seizure, condemnation, or destruction of any of the seized articles.

Claimant's General Manager, Michael W. Curtis, Plant Manager, Robert D. Schroeder, and Quality Control Compliance Manager, Jennifer J. Funkhouser, and Claimant (collectively, "Defendants"), without admitting or denying the allegations in the Complaint, now consent to the entry of this Decree without contest, before any testimony has been taken, and hereby waive the filing and service of an amended complaint seeking injunctive relief.

This Decree applies solely to Defendants and articles of dry milk powder or buttermilk powder (collectively, "milk powder products") that are or have been manufactured, processed, packed or held at Claimant's facility located at 412 E King Street, Strasburg, Virginia and/or any facility at which in the future the Claimant manufactures, processes, packs or holds milk powder products (hereinafter "facilities"). Nothing in this proceeding shall apply to the fluid dairy products produced at Claimant's facilities.

Whereupon, the Court being fully advised, it is on motion of the parties hereto,

ORDERED, ADJUDGED AND DECREED as follows:

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334, and personal jurisdiction over all parties to this action. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1395.

SEIZURE PROVISIONS

2. The Seized Articles are hereby condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

3. Pursuant to 21 U.S.C. § 334(e), the United States of America shall recover from the Claimant all court costs and fees, storage and other proper expenses already incurred with respect to the condemned articles, and such additional expenses as may hereafter be incurred and taxed pursuant to the authority set forth in 21 U.S.C. § 334. Claimant shall pay these costs within ten (10) calendar days after receiving notice of such costs from the United States Food and Drug Administration ("FDA"), the United States Marshals Service (the "USMS"), and/or the United States Department of Justice ("DOJ").

4. Within twenty (20) calendar days after entry of this Decree, Claimant shall execute and file with the Clerk of this Court a good and sufficient penal bond with surety, in a form acceptable to the Clerk of this Court and payable to the United States of America, in the amount of two hundred and fifty thousand dollars ($250,000.00), conditioned on the Claimant's abiding by and performing all of the terms and conditions of this Decree with respect to the condemned articles and such further Decrees or Orders as may be entered in this proceeding with

respect to the condemned articles. The bond shall be applied to Lot 1 as defined in the Reconditioning Plan to be submitted and approved under paragraph 6 of this Decree, and held for application to each successive lot as defined in the Reconditioning Plan.

5. Claimant shall provide all necessary documentation to verify the content and value of each lot of the condemned articles of food.

6. After the filing of the bond with this Court, the Claimant shall give written notice to the Baltimore District Office pursuant to paragraph 31, that Claimant, at its own expense, is prepared to attempt to bring the condemned articles into compliance with the Act under the supervision of a duly authorized representative of the FDA. Claimant shall not commence, permit any other person to commence, or cause any other person to commence attempting to bring the condemned articles into compliance with the law unless and until Claimant: (a) submits a written statement to FDA detailing Claimant's proposed plan to bring the condemned articles into compliance (the "Reconditioning Plan"), including a schedule for the proposed reconditioning; (b) receives written approval of the Reconditioning Plan from FDA; and (c) receives written authorization from FDA to commence attempting to bring the condemned articles into compliance with the law under the supervision of FDA. Such Reconditioning Plan may also include disposition of recalled and returned milk powder products. Claimant shall submit its Reconditioning Plan to FDA within one hundred twenty (120) calendar days after filing its bond with the Court. FDA will, if requested by the Claimant, respond to specific questions about the contents of the Reconditioning Plan in a telephone call to be held at a mutually agreed-upon time. In addition, once submitted, FDA will provide initial feedback on

the Reconditioning Plan to the Claimant orally within fifteen (15) business days of receipt. If warranted based on the initial oral feedback, the Claimant may submit a revised Reconditioning Plan to FDA. FDA's initial comments shall not bind the agency's final determination of whether, following implementation of the Reconditioning Plan, the product is in compliance with the law. FDA shall approve, reject, or provide other feedback on the Reconditioning Plan in writing within thirty (30) calendar days of receipt of the Reconditioning Plan, or if a revised Reconditioning Plan is submitted, within thirty (30) calendar days of receipt of the revised Plan.

7. The Claimant shall at all times, until the condemned articles have been released by FDA, retain intact each lot of condemned articles for examination or inspection by FDA, and shall maintain the records or other proof necessary to establish the identity of the articles comprising each lot to the satisfaction of FDA.

8. If a Reconditioning Plan is approved by FDA pursuant to paragraph 6, the United States Marshal for this District shall successively release each specified lot of the condemned articles to the Claimant for the sole purpose of attempting to bring such articles into compliance with the law. After release of the first lot, subsequent lots shall be released by the United States Marshal to the Claimant for the sole purpose of reconditioning, if and only if Claimant complies with all of the terms of this Decree with respect to each previously-released lots, and each such lot has been successfully reconditioned or destroyed pursuant to paragraph 10(b) of this Decree.

9. Within one (1) year of approval of the Reconditioning Plan, Claimant shall complete the process of attempting to bring the condemned articles into compliance with the law under the supervision of FDA. Unless an extension of time is mutually agreed to in writing by

FDA and the Claimant, Claimant shall destroy, at its own expense and under the direct supervision of an FDA representative, all condemned articles that have not been brought into compliance with the law within one (1) year of approval of the Reconditioning Plan, and shall file a notice with the Court certifying that such condemned articles have been destroyed.

10. The Claimant shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of any part of the condemned articles until: (a) FDA has had free access to them in order to take any samples or make any tests or examinations that are deemed necessary, and (b) their disposition has been approved by FDA in writing either because (1) the condemned articles have been successfully reconditioned according to the Reconditioning Plan approved by FDA; or (2) the condemned articles are going to be destroyed by a method approved by FDA.

11. If requested by FDA, Claimant shall furnish duplicate copies of invoices of sale of the released articles, or such other evidence of disposition as FDA requests.

12. If Claimant breaches any conditions stated in this Decree or in any subsequent Decree or Order in this proceeding with respect to the condemned articles, Claimant shall return the condemned articles immediately to the United States Marshal for this District at Claimant's expense, or shall otherwise dispose of them pursuant to an Order of this Court.

13. Claimant shall not sell or dispose of the condemned articles or any part of them in a manner contrary to the provisions of the Act, or other laws of the United States, or of any State or Territory (as defined in the Act), in which they are sold or disposed.

14. Claimant shall reimburse the United States of America for the cost of supervision, inspection, review, examination, and analyses conducted pursuant to this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date this Decree is signed by the parties, these rates are: $93.26 per hour and fraction thereof per representative for inspection and supervision work; $111.77 per hour and fraction thereof per representative for laboratory and analytical work; 54 cents per mile for travel expenses for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination, or analysis are modified, these rates shall be increased or decreased without further order of the Court. Claimant shall pay any such costs within ten (10) calendar days after being presented with an invoice for such costs from the FDA, the USMS, and/or the DOJ.

15. In the event Claimant does not avail itself, in the manner and within the timeframes stated in this Decree, of the opportunity to: (A) post a good and sufficient penal bond with surety with this Court; (2) submit a Reconditioning Plan for the condemned articles to FDA; or (3) successfully bring the condemned articles into compliance with the law or destroy the condemned articles within one (1) year of the approval of the Reconditioning Plan, unless that time is extended by mutual consent, the United States Marshal for this District shall destroy the condemned articles and make due return to this Court regarding their disposition. Claimant shall bear the costs of storage and destruction that are incurred by the United States pursuant to

this paragraph, and shall pay such costs within ten (10) calendar days of receiving an invoice from FDA, the USMS, or DOJ.

16. Should the Claimant fail to abide by and perform all the terms and conditions of this Decree or any such further Decree or Order as may be entered in this proceeding with respect to the condemned articles, then said bond shall, in its entirety, on motion of the United States of America in this proceeding, be forfeited to the United States of America and judgment entered thereon, and any condemned articles of food remaining in the custody of the United States Marshal shall be forfeited and disposed of pursuant to further Order of this Court.

17. The United States Attorney for this District, within fifteen (15) calendar days of being advised by FDA that the conditions of this Decree have been performed with respect to the condemned articles, shall transmit such information to the Clerk of this Court, whereupon the bond shall be cancelled and discharged.

INJUNCTION PROVISIONS

18. Defendants represent to the Court that, at the time of entry of this Decree, they are not engaged in manufacturing milk powder products at the Claimant's facility. If Defendants later intend to resume manufacturing milk powder products at any of Claimant's facilities, they must first notify FDA in writing at least ninety (90) calendar days in advance of resuming operations and comply with paragraphs 19(A)-(J) of this Decree.

19. Upon entry of this Decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations,

subsidiaries, affiliates, and partnerships) ("Associated Persons") who receive actual notice of this Decree, are hereby restrained and enjoined under 21 U.S.C. § 332(a) from: receiving, manufacturing, preparing, packing, holding, or distributing at or from any of Claimant's facilities, including but not limited to the facility located at 412 E King Street, Strasburg, Virginia, any article of dry milk powder or buttermilk powder (collectively, "milk powder products"), unless and until Defendants:

A. Establish and implement a written sanitation control program, which shall set out the details for sanitation control over the manufacturing and storage processes for the facilities used to receive, manufacture, prepare, pack, hold, or distribute milk powder products, and all food handling and storage equipment therein. The written sanitation control program shall be designed to ensure that the facilities and all equipment therein are maintained continuously in a sanitary condition to prevent conditions under which food may become contaminated with filth and/or may be rendered injurious to health or otherwise adulterated. The written sanitation control program must be approved in writing by FDA prior to implementation. Defendants shall assign responsibility for the implementation of the written sanitation control program to a person or persons who, by reason of education, training, and experience in sanitation work, are competent to maintain the facilities and all equipment therein in a sanitary condition. Such program shall, at a minimum include, but not be limited to, the provisions of subparagraphs (B)-(E) of this paragraph;

B. Thoroughly repair, clean and render Claimant's facilities and all equipment therein used to receive, manufacture, prepare, pack, hold, and distribute milk powder products

sanitary and fit for use in receiving, manufacturing, preparing, packaging, holding, and distributing of articles of food, and have in place adequate procedures to ensure that the facilities and all equipment therein are maintained continuously in such condition;

C. Clean and sanitize Claimant's facilities and all equipment therein used to receive, manufacture, prepare, pack, hold, or distribute milk powder products to effectively prevent microbial contamination of milk powder products, and adequately repair the floors, walls, doors, windows, and building in order to prevent reoccurrence of such microbial contamination;

D. Establish adequate methods and controls for receiving, manufacturing, preparing, packing, holding, and distributing milk powder products in Claimant's facilities that are designed to ensure that such articles of food do not become contaminated by microbial or physical contaminants;

E. Establish a regularly scheduled employee training program (no less frequently than every six months) to include, at a minimum, training in sanitary food handling techniques and personal hygiene practices

F. Develop and implement to FDA's satisfaction, a written Salmonella Monitoring Program that shall include, at a minimum, the following:

1. Effective sanitation methods and controls for receiving, manufacturing preparing, processing, packing, holding, and distributing milk powder products to minimize the risk of introducing Salmonella species ("spp.") and other pathogenic organisms into Defendants' food, and to ensure that foods are not adulterated within the meaning of 21 U.S.C. § 342(a)(4);

2. An effective program for environmental monitoring and testing of Claimant's facilities and milk powder products to ensure that organisms such as Salmonella spp. are systemically controlled and that Salmonella spp. does not occur in milk powder products. Sampling shall be conducted using specified frequencies and methods (e.g., how, where, and when to sample; the number and frequency of samples to be collected; the methods of analyses) that are approved by FDA prior to implementation. Defendants shall ensure that both the presumptive and confirmed positive results of all analyses conducted on samples from milk powder products are sent to FDA and the Virginia Department of Health[1] within two (2) business days after receipt by Defendants, together with a summary of steps taken by the Defendants to ensure that such milk powder products are not distributed. Defendants shall ensure that the results of all analyses conducted on samples from milk powder products are sent to FDA on a monthly basis. In the event that FDA determines at any point that it only wants to receive confirmed, positive sample results, the agency shall so notify Defendants;

3. An effective, written remedial action plan that Defendants shall implement should Salmonella spp., or any pathogenic organism be detected in milk powder products, including root cause analysis; and

4. Appropriate disposition of milk powder products that test positive for *Salmonella.*

G. Retain, at their expense, an independent laboratory having no personal or financial ties (other than the retention agreement) to Defendants or their families that is qualified

[1] The Virginia Department of Health, pursuant to Virginia law, permits and regulates Claimant's milk plant in Strasburg, Virginia. As of the entry of this Consent Decree, Claimant holds a grade A permit to operate a milk plant issued by the Virginia Department of Health.

to analyze environmental and product samples collected at Claimant's facilities for the presence of Salmonella spp. in a manner that is acceptable to the FDA. Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract.

H. Complete a trial run of the equipment and procedures, including manufacturing and processing limited quantities of milk powder products not for sale or distribution without written approval from FDA;

I. Report in writing to FDA at the address provided in paragraph 31 that Defendants have fully complied with the terms of subparagraphs (A)-(H) of this paragraph; and

J. Within four (4) weeks of providing the report referenced in subparagraph I, receive written notification from FDA stating that Defendants appear to be in compliance with the requirements set forth in subparagraphs (A)-(H), the Act, and all applicable regulations.

20. Upon entry of this Decree, Defendants and each and all of their Associated Persons who receive actual notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342; or

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342 while such articles are held for sale after shipment of one or more of their components in interstate commerce.

21. Within thirty (30) calendar days after FDA has notified the firm in writing pursuant to paragraph 19(J) that it may resume operations:

A. Claimant shall retain at its own expense, an independent person or persons (the "Auditor") to conduct audit inspections of Claimant's facilities not less than once every six months for a period of one year and not less than once every twelve months for a period of two years thereafter, for a total of three years of auditing. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement entered into by the parties) to any of the Defendants, any of Claimant's officers or employees, or their immediate families. Defendants shall notify FDA of the Auditor's qualifications in writing as soon as the Auditor is retained.

B. The audit inspection shall evaluate and address all FDA inspection observations of deficiencies from November 7, 2013, to the present and in general determine whether Defendants are in compliance with the Act and applicable regulations, including, but not limited to, whether: (a) equipment and facility areas used in the manufacture of milk powder products are adequately maintained and cleaned; (b) whether employees follow proper sanitation procedures with respect to milk powder products; and (c) whether milk powder products are appropriately handled to minimize the risk of microbial contamination or cross contamination.

C. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") identifying in detail any deviations from the Act and applicable regulations ("Audit Report Observations"). As part of every Audit Report except the first Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to

correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants, the Virginia Department of Health, and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date each audit inspection is completed. If an Audit Report contains any Audit Report Observations, FDA may, in its discretion, require that the three year auditing cycle be extended by one year or until such Audit Report Observations have been corrected. In addition, Defendants shall maintain the complete Audit Reports and all of their underlying data in separate files at their facilities and shall make the Audit Reports and underlying data available to FDA promptly upon request.

D. If an Audit Report contains any Audit Report Observations, Defendants shall, within thirty (30) business days of receipt of the Audit Report, correct those observations, unless FDA notifies them that a shorter time period is necessary. If after receiving the Audit Report, Defendants believe that correction of an Audit Report Observation will take longer than thirty (30) business days, Defendants shall, within fifteen (15) business days of receipt of the Audit Report, propose to FDA a schedule for completing corrections ("Correction Schedule") and provide justification describing why the additional time is necessary. FDA shall, within ten (10) business days of receiving the proposed Correction Schedule, review and approve or disapprove the Correction Schedule in writing. If FDA does not approve the Defendants' first proposed Correction Schedule, Defendants shall submit a revised Correction Schedule to FDA within three (3) business days of receiving notice of FDA's disapproval. FDA shall, within ten (10) business days of receiving the revised Correction Schedule, review and approve or disapprove the revised Correction Schedule in writing. If FDA does not approve Defendants' revised Correction

Schedule, Defendants shall correct all Audit Report Observations within three (3) business days of receiving notice of FDA's disapproval, unless FDA notifies them in writing that a longer time period is acceptable. Defendants shall complete all corrections according to the approved Correction Schedule.

E. Within sixty (60) business days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within ten (10) business days of the completion of that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected.

22. If at any time after entry of this Decree, FDA determines, based on the results of an inspection, Audit Report, or other information, that Defendants are not compliance with the Act, applicable regulations, or this Decree with respect to their milk powder products, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate corrective actions, including, but not limited to, the following:

A. Discontinue all receiving, manufacturing, preparing, packing, holding, and distributing milk powder products at that facility;

B. Recall, at Claimant's expense, any milk powder product that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA; and/or

E. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

23. The following process and procedures shall apply when FDA issues an order under paragraph 22:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless the Court stays, reverses, or modifies

FDA's order. Any review of FDA's decision under this paragraph shall be made pursuant to paragraph 26.

D. The process and procedures set forth in subparagraphs (A)-(C) of this paragraph shall not apply to any order issued pursuant to paragraph 22 if such order states that, in FDA's judgment, the order raises significant public health concerns. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition the Court for relief while they implement FDA's order. Any review of FDA's decision under this paragraph shall be made pursuant to paragraph 26.

24. Any cessation of operations or other action described in paragraph 22 shall be issued by FDA's Baltimore District Director, or a person acting in that capacity, and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may, therefore, resume operations. The costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraph 22 shall be borne by Claimant at the rates specified in paragraph 14 of this Decree.

25. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of any of Claimant's facilities, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to

buildings, equipment, articles of food, containers, and packaging material(s) therein; to take photographs and make video recordings; to take samples of Defendants' articles of food, containers, and packaging material(s); to examine and copy all records relating to the receiving, manufacturing, preparing, packing, holding, and distributing of any and all articles of food, and to the sanitation of the facility. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

26. Defendants shall abide by the decisions of FDA and its representatives with respect to this Decree, which decisions shall be final. All decisions specified in this Decree shall be vested in FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by a court of any FDA decision rendered pursuant to this Decree shall be based exclusively upon the written record that was before FDA at the time of the decision. No discovery shall be taken by either party.

27. Defendants shall provide a copy of this Decree, by personal service or by delivery via electronic mail with acknowledgement of receipt, or when necessary, by certified mail (restricted delivery, return receipt requested), within ten (10) calendar days from the date of entry of the Decree, to each of their Associated Persons. Defendants shall also post a copy of this Decree in the employee common areas at each of Claimant's facilities as long as it remains in effect. Within thirty-five (35) calendar days after entry of this Decree, Defendants shall provide

to FDA an affidavit of compliance with this paragraph, stating the facts and manner of compliance with the provisions of this paragraph. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree by personal service or by delivery via electronic mail with acknowledgement of receipt, or when necessary, by certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time any Defendant becomes associated with an additional Associated Person(s), it shall, within ten (10) business days, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA

28. Defendants shall notify FDA in writing at least thirty (30) calendar days before any change in location, ownership, or character of their business, such as reorganization, dissolution, assignment, or sale resulting in the emergence of a successor corporation or business entity, the creation or dissolution of subsidiaries, or any other change in the corporate or business structure of any newly-formed business entity (including any "doing business as" entity) over which Defendants have any authority, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any successor or assignee at least thirty (30) calendar days

prior to the assignment or change in ownership. Defendants shall furnish FDA with an affidavit of compliance with this paragraph at least thirty (30) calendar days prior to such assignment or change in ownership.

29. Should Defendants fail to comply with any provision of the Act or its implementing regulations, or any provision of this Decree, then, on motion of the United States in this proceeding, Claimant shall pay to the United States of America: one thousand dollars ($1,000) in liquidated damages for each day such violation continues; an additional sum of one thousand dollars ($1,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; and an additional sum in liquidated damages equal to twice the retail value of any shipments of adulterated food. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for the payment of liquidated damages pursuant to this paragraph.

30. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants agree to pay all attorney's fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such an action.

31. All notifications, correspondence, and communications to FDA, DOJ, and/or the Virginia Department of Health required by the terms of this Decree may be sent by electronic mail with acknowledgment of receipt and shall be addressed to, as appropriate:

District Director
Baltimore District Office
U.S. Food and Drug Administration
Department of Health and Human Services
6000 Metro Drive, Suite 101
Baltimore, MD 21215

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Roanoke, VA 24008-1709

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P.O. Box 386
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Julie Henderson
Director of Food and General Environmental Services
Office of Environmental Health Services
Virginia Department of Health
109 Governor Street 5th Floor
Richmond, VA 23219

32. This Court retains jurisdiction to issue such further Decrees and Orders as may be necessary to the proper disposition of this proceeding.

33. No sooner than five (5) years after entry of this Decree, Defendants may petition this Court for an order dissolving the Decree. If Defendants have maintained to FDA's

satisfaction a state of continuous compliance with this Decree, the Act, and all applicable regulations during the five (5) years preceding Defendants' petition, the United States of American will not oppose such petition.

SO ORDERED

Dated this 14th day of March 2017.

/s/ Elizabeth K. Dillon
United States District Judge

We hereby consent to the entry of the foregoing Decree.

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